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10/560,210	05/05/2006	Robert Short	P-7717	2947

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EXAMINER	
HAQ, SHAFIQUL	
ART UNIT	PAPER NUMBER
1641	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,210	SHORT ET AL.	
	Examiner	Art Unit	
	SHAFIQUL HAQ	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *85 and 87-122* is/are pending in the application.

4a) Of the above claim(s) *88,89,95,97-101,104-107 and 110* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *85, 87, 90-94, 96, 102-103, 108-109 and 111-122* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other. _____.

DETAILED ACTION

1. Applicants' amendments and arguments filed 8/10/09 is acknowledged and entered. Claims 85 and 87-122 are pending of which claims 88, 89, 95, 97-101, 104-107 and 110 are withdrawn from further consideration as being directed to a non-elected species. See 37 CFR 1.142(b) and MPEP § 821.03 (see Applicants election of species filed 7/10/08 and office action of 11/3/08)..
2. Claims 85, 87, 90-94, 96, 102-103, 108-109 and 111-122 are examined on merits in this office action.

Rejections Withdrawn

3. Applicant's arguments, see p1, filed on August 10, 2009, with respect to the rejections of claims 85-87, 90-94, 96, 102, 103, 108, 109 and 111-122 under 35 U.S.C. 112, first paragraph have been fully considered and are persuasive. The rejection of claims 85-87, 90-94, 96, 102, 103, 108, 109 and 111-122 under 35 U.S.C. 112, first paragraph has been withdrawn in view of amended claim 85 in the reply filed on August 10, 2009.

4. Applicant's arguments, see p1, filed on August 10, 2009, with respect to the rejection of claim 120 under 35 U.S.C. 112, first paragraph have been fully considered and are persuasive. The rejection of claim 120 under 35 U.S.C. 112, first paragraph has been withdrawn in view of amended claim 120 in the reply filed on August 10, 2009.

5. Applicant's arguments, see p1, filed on August 10, 2009, with respect to the rejections of claims 85-87, 90-94, 96, 102, 103, 108, 109 and 111-122 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The

rejection of claims 85-87, 90-94, 96, 102, 103, 108, 109 and 111-122 under 35 U.S.C. 112, second paragraph has been withdrawn in view of amended claim 85 in the reply filed on August 10, 2009.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 85, 87, 96, 102, 103, 108, 121 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winter-Jensen (WO 02/32591).

Winter-Jensen discloses a method of preparing a material for binding of biomolecules comprising coating a polymer gradient on at least a part of the surface of a substrate by plasma polymerization process (see "Abstract and "FIELD OF THE INVENTION") wherein the plasma polymerization process involves steps of moving the part of the substrate on which the plasma polymerization is intended relative to the reaction chamber (page 14, lines 4-14). Winter-Jensen teaches that the substrate is moved in the direction corresponding to the direction of the desired gradient. Jensen *et al* further teach that the polymer coating gradient may be in the form of a polymer coating which varies in chemical composition so that is varies along the surface of the substrate in a graduating pattern, preferably so that the composition is varied in concentration of one or more components and/or in the form of a mixture of two or more compounds which is varied with respect to the amount of

the respective compounds stepwise or continuously along the surface of the substrate (page 7, lines 26-31). Winter-Jensen teaches that monomers for plasma coating may be mixtures of monomers including at least mixtures of acrylic acid and cyanoacrylate, mixtures of acrylic acid and ethylene diamine, mixturess of acrylic acid and allylamine, or mixtures of vinyacetic acid and allylamine and the plasma polymer comprising the above monomeric mixtures would be capable of attaching biomolecules as the polymeric surface would contain functional groups. That is Winter-Jensen teaches deposition of non-uniform plasma polymer (heterogeneous chemically and physically) wherein the coating process includes binding entity (i.e. a functional group: see specification which states that binding entity may comprise a chemical functional group such as a carboxyl or amine functional group: page 4, lines 25-26). However, Jensen *et al* do not disclose coating of the plasma polymer separately with a binding entity.

However, coating the binding entity separately or simultaneously for preparing the non-uniform coated surface, is viewed as routine variation in sequence of processing and as optimization process and which have not been described as critical to the practice of the invention and thus is obvious over the prior art. See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

Further, Jensen *et al* separation of proteins (i.e. binding entity comprising carboxyl and amine functional group) from complex mixture (page 1, lines 4-17) using the substrate and during the method of separation, a heterogeneous surface would be produced wherein binding entity (i.e. proteins) would be coated on the plasma polymer through the functional groups.

With regard to claims 86, 96, 102 and 108, Winter-Jensen teaches acrylic acid for plasma monomer, which comprises a carboxyl group and acrylic acid is considered as a volatile acid.

With regard to claim 103, Winter-Jensen teaches that preferred polymer gradient coating being made from monomers selected the group consisting of acrylic adic, methacrylic acid and vinylacetic acid (page 9, lines 8-11), which provides one to select a single monomer for the polymer coating.

With regard to claims 121 and 122, Winter-Jensen teaches that the substrate may be selected from plyethylene, polypropylene, silicon rubbers, glass, paper and metals (page 6, lines 8-13).

8. Claims 90-93, 109 and 112-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winter-Jensen (WO 02/32591) in view of Chu *et al* (Materials Science and Engineering 2002) and further in view of Timmons *et al* (US 5,876,753).

See the above teaching of Winter-Jensen (WO 02/32591). Winter-Jensen teaches providing hetorogeneous surface from plasma monomer but does not mention about the bond formation of the plasma monomers and bonding to biomolecuels (e.g. binding entities).

Chu *et al* teach modification of biomaterial surface using plasma deposition (see title) and teach mechanism of plasma polymerization process which involves activation of monomers to radicals, recombination of the formed radicals and reactivation of the recombined radicals providing cross-linked, fragmented and rearranged units from the monomers (paragraph 2.2.3.2). Therefore, plasma polymerization involves covalent bond formation between the plasma monomers and thus forms co-polymers from different plasma monomers.

Timmons *et al* (US 5,876,753) teach methods of plasma deposition of reactive functional groups (column 9, lines 4-24) on a surface of a solid support to provide reactive surface (see abstract) followed by chemical derivation process in which desired molecules are covalently bound to the surface via simple chemical reaction (column 3, lines 40-44). Timmons *et al* teach deposition heterogeneous organic compounds comprising functional group using plasma deposition process and target materials (e.g. proteins, peptides, saccharides, hormones, receptors, polynucleotides, oligonucleotides, carbohydrates etc.) added to the activated surface by reaction with the reactive group (column 3, lines 46-56; column 4, lines 29-36; column 6, lines 1-26 and column 10, lines 1).

Therefore, given the fact that plasma polymerization involves covalent interactions among plasma monomers (Chu *et al*), one of ordinary skill in the art, from the information of the polymerization process at taught by Chu, would readily appreciate co-polymer formation among the plasma monomers of Winter-Jesen having bonded covalently and since specification states that binding entity may

comprise a chemical functional group such as a carboxyl or amine functional group (page 4, lines 25-26), one of ordinary skill in the art would consider carboxyl containing plasma monomer as binding entity in monomeric mixture for plasma deposition in the method of Winter-Jensen because Winter-Jesen teaches that monomers for plasma coating may be mixtures of monomers including at least mixtures of acrylic acid and cyanoacrylate, mixtures of acrylic acid and ethylene diamine, mixturess of acrylic acid and allylamine, or mixtures of vinyacetic acid and allylamine and the plasma polymer comprising the above monomeric mixtures would be capable of attaching cells as the polymeric surface would contain a functional group such as carboxylic group. Therefore, the immobilization, linkage and covalent bond formations of the binding entity as claimed in claims 90-93 are considered as obvious interactions in view of the known teaching of Winter-Jensen and Chu *et al*. Further, the derivatization of the plasma deposited surface of Winter-Jensen with binding entity such as proteins, nucleic acids, hormones etc. would also be obvious to one or ordinary skill in the art because Winter-Jensen surface is for binding of organic compounds such as proteins (page 1, lines 5-7) and Timmons *et al* teach that functionalized plasma polymerized surface can be derivatized with various binding entities such as proteins, nucleic acids, hormones etc. (column 4, lines 29-47) to provide solid surface comprising binding entities (column 3, lines 46-47).

With regard to claim 87, Timmons *et al* teach deposition heterogeneous organic compounds comprising functional group using plasma deposition process and target materials (e.g. proteins, peptides, saccharides, hormones, receptors,

polynucleotides, oligonucleotides, carbohydrates etc.) added to the activated surface by reaction with the reactive group (column 3, lines 46-56; column 4, lines 29-36; column 6, lines 1-26 and column 10, lines 1) and with regard to claim 109, as described above, Chu *et al* teach mechanism of plasma polymerization process which involves activation of monomers to radicals, recombination of the formed radicals and reactivation of the recombined radicals providing cross-linked, fragmented and rearranged units from the monomers (paragraph 2.2.3.2). Therefore, plasma polymerization involves covalent bond formation between the plasma monomers and thus forms co-polymers from different plasma monomers.

With regard to claims 112-119, as described above, Winter-Jensen teaches a means for moving the substrate through the reaction chamber (page 13, lines 17-19) and control of the reaction chamber (page 13, lines 30-31) for providing heterogeneous surface and Chu *et al* teach providing patterned plasma polymerized surface (see Fig. 15) and therefore, different patterns (e.g. lines, dots) of plasma polymerized surface as required by different applications would be a matter of judicious selection and obvious design choice which is well within the purview of the skilled artisan and therefore obvious under 35 U.S.C. § 103(a).

9. Claims 94 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winter-Jensen (WO 02/32591) in view of Haddow et al (WO 03/035850) and Uhrich et al (US 2003/0104614).

See the above teaching of Winter-Jensen for a substrate wherein the substrate comprises a non-uniform plasma polymerized surface. Winter-Jensen fail to teach binding of cells to the plasma polymerized surface.

Haddow *et al* disclose plasma polymerized surface having functional groups (e.g. carboxylic acid, alcohol) (page 4, lines 1-2) useful for adhering and culturing cells (abstract and page 4, lines 28-30). Haddow *et al* teach that by plasma polymerization, it is possible to modify surface chemistry without affecting the bulk properties of the substrate and to deposit a range of different types of surfaces (page 4, lines 18-24) and is advantageous because the surface have unique chemical and physical characteristics (page 3, lines 3-4 and page 4, lines 25-26). Haddow *et al* teach the surface produced by plasma polymerization is particularly useful as a substrate for cell culture (page 5, lines 21-25; page 13, lines 13-25).

Uhrich *et al* teach patterned areas of a substrate for making patterns of biologically active molecules useful for spatially directing cell growth, tissue regeneration, screening studies and multiple analytical biosensor (see abstract and paragraph [0002]).

Therefore, given the fact that plasma polymerized surface is useful for adhering and growth of cells (Haddow *et al*) and culturing of cells in a pre-selected region (i.e. patterned surface) is very useful and known in the art (Uhrich *et al*), it would be obvious to one of ordinary skill in the art at the time the invention was made to consider providing Winter-Jensen with patterned plasma polymerized surface for adhering of cells because Haddow *et al* teach plasma polymerized surface is useful

for cell attachment and culture and because patterns can be provided by movement of the substrate relative to source of plasma (Winter-Jensen *et al.* Since, Winter-Jensen teaches that various functional groups can be introduced during plasma polymerization using different polymerisable monomers and patterned surfaces with desired functional groups as needed for attachment of various biomolecule can be produce with the plasma deposition process of Winter-Jensen.

With regard to claims 94, Haddow et al teach attachment of cells to plasma polymerized surface (page 4, lines 1-2, 18-20 and page 5, lines 17-27) and cells comprises carboxyl or amine functional group.

With regard to claim 111, Haddow *et al* disclose polymerizable monomers having vapour pressures of at least $6.6X10^{-2}$ mbar (page 7, lines 9-12).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 85, 86, 87, 90-94, 96, 102, 103, 108, 109 and 111-122 are again provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 41-77 of copending Application No. 10/509,431 in view of in view of Haddow et al (WO 03/035850) and Uhrich et al (US 2003/0104614).

Claim 41 of copending application 10/509,431 discloses a method for preparing a heterogenous surface on a substrate comprising: depositing a plasma polymer on the substrate using at least one organic compound monomer as a source of plasma; and moving at least one of:

(i) the source of plasma, and

(ii) the substrate,

relative to one another during plasma deposition such that at least part of the substrate has a plasma polymer deposit that has non-uniform characteristics selected from the group consisting of being heterogenous chemically, heterogeneous physically, and combinations thereof to define the heterogeneous surface.

Claims of the copending application 10/509,431 do not disclose coating at least part of the plasma polymer deposit with a binding entity comprising carboxyl or an amine functional group.

Haddow *et al* disclose plasma polymerized surface having functional groups (e.g. carboxylic acid, alcohol) (page 4, lines 1-2) useful for adhering and culturing cells (i.e. binding entity comprising carboxyl or amine functional group) (abstract and page 4, lines 28-30). Haddow *et al* teach that by plasma polymerization, it is possible to modify surface chemistry without affecting the bulk properties of the substrate and to deposit a range of different types of surfaces (page 4, lines 18-24) and is advantageous because the surface have unique chemical and physical characteristics (page 3, lines 3-4 and page 4, lines 25-26). Haddow *et al* teach the surface produced by plasma polymerization is particularly useful as a substrate for cell culture (page 5, lines 21-25; page 13, lines 13-25).

Uhrich *et al* teach patterned areas of a substrate for making patterns of biologically active molecules useful for spatially directing cell growth, tissue regeneration, screening studies and multiple analytical biosensor (see abstract and paragraph [0002]).

Therefore, given the fact that plasma polymerized surface is useful for adhering and growth of cells (Haddow *et al*) and culturing of cells in a pre-selected region (i.e. patterned surface) is very useful and known in the art (Uhrich *et al*), it would be obvious to one of ordinary skill in the art at the time the invention was made to consider the plasma polymerized surface of the copending application for adhering of cells (i.e. binding entity comprising carboxyl or amine groups) because Haddow *et al* teach plasma polymerized surface is useful for cell attachment and culture and

because patterns can be provided by movement of the substrate relative to source of plasma.

With regard to claims 86-87, cells comprise amine and carboxyl functional group (see paragraph [0029] of Uhrich's) and with regard to claims 90-94, Haddow *et al* teach providing various functional group on plasma polymerized surface for attachment of cells (page 2, lines 30-31; page 4, lines 1-2 and 28-30) and thus various interaction of cells with the functional groups such as covalent and no-covalent interaction would to obvious to one of ordinary skill in the art absent unexpected results.

With regard to claims 94, Haddow et al teach attachment of cells to plasma polymerized surface (page 4, lines 1-2, 18-20 and page 5, lines 17-27) and cells comprises carboxyl or amine functional group.

With regard to claims 96, 103, 108, 109 and 111-122, the various limitations are disclosed in claims of the copending application and while limitations are claimed in different orders, the various limitations of the present claims 96, 103, 108, 109 and 111-122, are also claimed in this copending case,

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to argument

12. Applicant's arguments and amendments filed 8/10/09 have been fully considered and are persuasive to overcome the rejections of 5/12/09 under 35 U.S.C. 112 second paragraph and the rejection under 35 U.S.C 112, first paragraph. However,

applicant's amendments necessitated modifying the rejections under 35 USC 103 (a) to address the incorporated claim limitations and the rejection is maintained for the reasons as set forth in the rejection as described in this office action.

Conclusion

13. No claims are allowed.

14. Applicants' amendment necessitated new ground(s) of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicant should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (e.g., if the amendment is not supported in ipsis verbis,

clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAFIQUL HAQ whose telephone number is (571)272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shafiqul Haq/
Primary Examiner, Art Unit 1641